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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,078	06/23/2006	Per Thor Straten	HOIB1.001APC	9104
20995 7590 12/27/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			NOTIFICATION DATE 12/27/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/553,078

Applicant(s)

STRATEN ET AL.

Examiner

Anne M. Gussow

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45 and 54-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/22/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,7,12,14-16,18-21,24,27,30,32,33,35,37,39,41,45,47-49,51 and 53-65.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,2,4,7,12,14-16,18-21,24,27,30,32,33,35,37,39,41,47-49,51 and 53.

DETAILED ACTION

1. Claims 45 and 49 have been amended.

Claims 60-65 have been added.
2. Claims 45 and 54-65 are under examination.
3. The following office action contains NEW GROUNDS of Rejection.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on October 22, 2007 was filed after the mailing date of the first action on the merits on July 20, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner and an initialed copy of the IDS is included with the mailing of this Office Action.

Objections Withdrawn

5. The objection to the oath is withdrawn in view of applicant's arguments.
6. The objections to the specification are withdrawn in view of applicant's amendments to the specification.

Rejections Withdrawn

7. The rejection of claims 45 and 54-59 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment to the claims and arguments.

Rejections Maintained/NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 54-57 recite the limitation "said fragment" in line 1. There is insufficient antecedent basis for this limitation in the claims.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. The rejection of claims 45 and 54-59 and newly added claims 60-65, under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed October 22, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the Examiner has applied a standard of proof to which the claims do not relate. In several situations the Examiner seems to interpret "a specific T-cell response" as stated in Claim 45 as "a response of tumor cell lysis in vivo" or even as "a response capable of eliminating tumors

completely." Although desirable, these results are not elements of the pending claims. An anti-tumor CTL response is indeed the ultimate goal of the technology, but Applicants do not claim a measurable anti-tumor response in every instance of administration of one of a claimed polypeptide to a patient. The claims specify polypeptides that are capable of raising a specific T-cell response against that epitope. The claims do not require that the all specific T-cell responses will result in tumor cell destruction by CTL's in all cases (see response page 14).

In response to this argument, when given the broadest reasonable interpretation the claims read on in vivo treatment. One of skill in the art would expect the specific T cell response to be effective in treating a condition, in this case a tumor.

The response also questions the relevance and age of the references cited by the examiner (see response pages 15-16).

In response to this argument, the age of the reference is irrelevant providing they are supportive of the rejection. Regarding the relevance of the references, the correlation of specific antibody production to as specific T-cell response is irrelevant to the claims because antibodies are produced by B cells and are not directly involved in a T-cell specific response. The instant claims are not drawn to a B-cell response, thus the production of antibodies is irrelevant. Additionally, the argument that ML-IAP is not a self protein is incorrect, while ML-IAP may be a cancer-specific protein, cancer cells are "self" cells and therefore all cancer proteins are self proteins and may be recognized as self by the immune system, therefore, not targeted in an anti-cancer immune response.

Regarding the specific references cited by applicant, these references are directed to in vivo induction of a T-cell response even though applicant argues that the

claimed invention does not read on in vivo treatment. In each of the references, only a limited number of the peptides tested induce a T-cell response. Applicant's argument that the vaccines may be used in combination with other therapies is not a limitation of the instant claims.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

12. The rejection of claims 45 and 54-49 and newly added claims 60-65 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed October 22, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the functional equivalents are variants having at least 75 % sequence identity to the peptides identified by the SEQ ID Nos listed. This level of sequence identity to the peptides identified by SEQ ID Nos is maintained to help ensure that the antigenic properties of the peptides are conserved. The Skolnick reference cited by the examiner as support for the inaccuracy of "assigning functional activities for any particular protein or protein family based upon sequence homology" is not relevant in this connection due to the fact that peptides of 9-15 amino acids in length are almost certain to have no folding or other significant tertiary structure, and therefore are not proteins with functional activities as discussed by Skolnick (see response page 17).

In response to this argument, in small peptides, while there is no tertiary or higher order structure in the molecule, each individual residue is important in

contributing to the function of the molecule. While minor conserved changes may be made, it is not absolute that mutation of each and every residue, even if only one at a time, would maintain the function of the molecule. Applicant has not provided evidence that at the time the invention was made, they were in possession of variants of the claimed peptides that would be effective for inducing a T-cell response.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 11, 2007

/Larry R. Helms/
Supervisory Patent Examiner